



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

November 26, 2013

SteriTec Products Manufacturing Company, Incorporated  
Mr. Jonathan Rutigliano  
Director, Regulatory Affairs  
74 Inverness Drive East  
Englewood, Colorado 80112

Re: K132372  
Trade/Device Name: SteriTec Green Card Pack Bowie-Dick Test, Model BD 126  
Regulation Number: 21 CFR 880.2800  
Regulation Name: Sterilization process indicator.  
Regulatory Class: II  
Product Code: JOJ  
Dated: October 24, 2013  
Received: August 26, 2013

Dear Mr. Rutigliano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**ErinFDKeith**

Erin Keith, M.S.  
Acting Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K132372

Device Name  
SteriTec Green Card Pack Bowie-Dick Test

**Indications for Use (Describe)**

SteriTec Green Card Pack Bowie-Dick Test is a single use device designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 132°C and 134°C for 3.5 minutes. The indicator card within the Green Card Pack will demonstrate a uniform color change from purple to green when proper sterilization conditions are met and no air is present. If enough air is present to create a 2° C (+1°/-0° C) temperature difference between the center of the towel pack, as identified in ANSI/AAMI/ISO 11140-5, and the drain temperature at the beginning of the final one minute of a three and half minute cycle the indicator card within the Green Card Pack will demonstrate a non-uniform color change.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth F. Claverie  
2013.11.26 00:07:54 -0500